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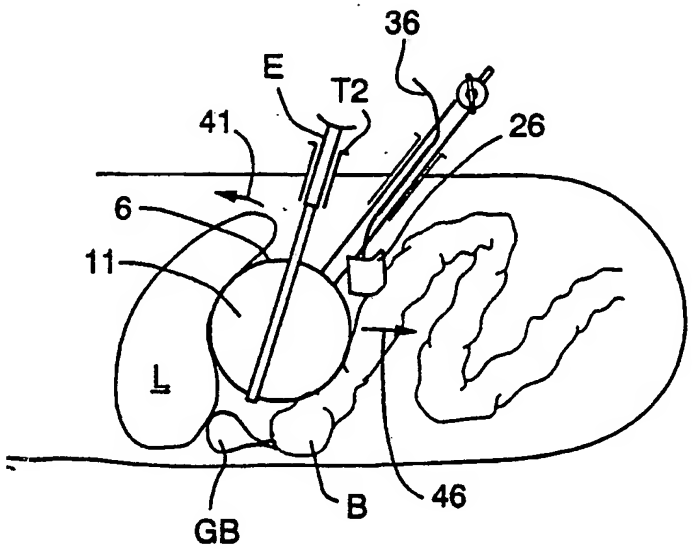

(57) Abstract

Inflatable retraction devices for use in laparoscopic surgery are inserted into the body in a collapsed state adjacent to an organ, and are inflated into an expanded state to retract the organ to provide access to treat a tissue. In a first variation, the inflatable retraction device retracts the organ by exerting a force against adjacent organs. In a second variation, the inflatable retraction device retracts the organ by providing a retraction force from outside the body. An inflatable retraction device that provides the retraction force from outside the body can be made using a Foley catheter.

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ENDOSCOPIC INFLATABLE RETRACTION DEVICES, METHODS OF USING, AND A METHOD OF MAKING

Field of the Invention

The invention relates to devices for use in laparoscopic surgery, in particular, to devices that provide retraction of an organ to gain access to treat or observe a tissue.

Background of the Invention

Laparoscopy dates back to the turn of the 20th Century. Early laparoscopic techniques were used primarily for diagnostic purposes to view the internal organs, without the necessity of conventional surgery. Since the 1930s, laparoscopy has been used for sterilization and, more recently, for the suturing of hernias. U.S. Patents 4,919,152 and 4,944,443 are concerned with techniques for suturing hernias. Another very recent innovation is the use of laparoscopic surgery for removing the gallbladder.

United States Patent Application Serial No. 706,781, of which application, the parent of this application is a Continuation-in-Part, describes an apparatus and method wherein the abdominal wall is lifted away from the underlying abdominal organs by an inflatable device which is introduced laparoscopically and, once in place, inflated to engage and lift an extensive area of the abdominal wall.

Even when such lifting techniques are used, it is still necessary to retract other organs to gain access to the organ or tissue to be treated or observed. In other procedures, to gain access to the organ or tissue to be treated or observed, it is necessary to separate the organ to be treated from tissue surrounding it. For example, to be able to observe the outer surface the heart, the outer surface of the heart has to be separated from the pericardium.

United States Patent Application Serial No. 794,590, the application of which this application is a Continuation-in-Part (the "parent application"), describes

inflatable retraction devices that retract organs or tissues by means of an inflatable chamber. The retraction device is introduced in a collapsed state into the body through a small incision, and, once in place, inflated to engage an extensive area of the organ or tissue to be retracted, and to gently retract or displace the organ or tissue without damaging it. During laparoscopic treatment and observation procedures, the retraction device retains its expanded condition, and hence its ability to provide retraction, while providing access for surgical instruments through itself to the organ or tissue being treated or observed, or allowing an organ or tissue to be brought inside itself for observation or treatment.

The inflatable retraction devices described in the parent application, and one of the inflatable retraction devices described in the present application, are placed in the body through a small incision, and, when inflated, retract the organ by pushing against other adjacent organs and tissues. The force exerted by the retraction device against other organs or tissues within the body cavity can sometimes cause trauma and even damage to the other organs. Hence, it is sometimes preferable to provide a retraction device that can introduced into the body through a small incision, and which provides retraction without exerting a force against other adjacent organs and tissues.

To provide a retraction from outside the body, current laparoscopic procedures use several small metal or plastic retractors inserted though a plurality of incisions. The retractors are fixed to a suitable bar to hold them in place once the desired amount of retraction has been achieved. Because such retractors have a relatively small surface area (the retractors have to be small enough to fit through a small incision), they tend to damage and/or cause trauma to the retracted organs. Moreover, the required plurality of incisions in the body wall undoes some of the advantage of using laparoscopic techniques.

Summary of the Invention

The present invention relates to inflatable retraction devices that mechanically retract organs and tissues to provide access to treat or observe other organs or tissues. In the following description, the word "organ" will be used to mean an organ or a tissue that is retracted by the retraction device. The word "treat" will be used to mean both treat and observe, and the word "treatment" will be used to mean both treatment and observation. The word "tissue" or the phrase "tissue

to be treated" will both be used to mean the organ or the tissue that is treated after the organ has been retracted.

An inflatable retraction device according to a first aspect of the invention retracts an organ inside the body to gain access to an adjacent tissue. The inflatable retraction device comprises an inflatable chamber that is capable of being inserted into the body in a collapsed state through a small incision. The inflatable chamber has a thin, flexible envelope. The apparatus also includes a device for selectively inflating the inflatable chamber to an expanded condition while in place within the body.

The inflatable retraction device is used in applications in which it can be placed so that it retracts the organ without obstructing access to the tissue being treated. Treatment of the tissue is carried out working around the retraction device. Surgical instruments are passed into the body through a second small incision, and pass around the outside of the retraction device to reach the tissue.

In a first method according to the invention of using an inflatable retraction device to retract an organ in the body in the course of treating an adjacent tissue, an inflatable retraction device is provided in a collapsed state. A small incision is made in the body and the inflatable retraction device in a collapsed state is introduced into the body through the small incision. The inflatable retraction device in a collapsed state is placed adjacent to the organ, and is inflated into an expanded state to retract the organ.

An inflatable retraction device according to a second aspect of the invention provides a retraction force from outside the body to retract an organ inside the body to gain access to an adjacent tissue. The inflatable retraction device comprises an inflatable chamber that engages with the organ, and a shaft for manipulating the inflatable chamber to retract the organ. The shaft has a distal end to which the inflatable chamber is attached, a bore that communicates with the inflatable chamber and allows the inflatable chamber to be inflated to an expanded state when the inflatable chamber is in place within the body. The shaft has a proximal end, which remains outside the body when the inflatable chamber is in place in the body.

In a first variation, the inflatable chamber is substantially spherical; in a second variation, the inflatable chamber is flat, and substantially oblong; and in a third variation, the inflatable retraction device comprises a Foley catheter with a stylet inserted into the tube of the catheter.

In a second method according to the invention for retracting, by means of a retraction force provided from outside the body, an organ in the body in the course of treating an adjacent tissue, an inflatable retractor is provided having an inflatable chamber, and a hollow shaft having a distal end and a proximal end. The inflatable chamber is attached to the distal end of the shaft in a collapsed state. A small incision is made in the body. The proximal end of the shaft is manipulated to pass the inflatable chamber and part of the shaft into the body through the small incision, and to place the inflatable chamber adjacent to the organ. A fluid is passed through the shaft to inflate the inflatable chamber into an expanded state. Finally, the proximal end of the shaft is manipulated to engage the organ with the inflatable chamber, and to retract the organ.

In a method according to the invention of making an inflatable retraction device, a Foley catheter having an inflatable chamber and a flexible tube is provided. A stylet is also provided, and is inserted into the flexible tube of the Foley catheter.

Brief Description of the Drawings

Figure 1A shows a free balloon inflatable retraction device according to the invention in its expanded state.

Figure 1B shows a free balloon inflatable retraction device according to the invention in its collapsed state.

Figure 2A is a longitudinal cross section of the abdomen showing a free balloon inflatable retraction device according to the invention in its collapsed state inserted into the abdomen through a small incision.

Figure 2B is a longitudinal cross-section of the abdomen showing a free balloon inflatable retraction device according to the invention in its expanded state providing access for an endoscope to the gall bladder.

Figure 2C is a partially cut-away plan view of the abdomen showing a free balloon inflatable retraction device according to the invention in its expanded state providing access for an endoscope to the gall bladder.

Figures 3A through 3E show an inflatable retraction device according to the invention that provides a retraction force from outside the body, wherein:

Figure 3A shows the inflatable retraction device with its inflatable chamber in its collapsed state outside the shaft.

Figure 3B shows the inflatable retraction device with its inflatable chamber in its collapsed state inside the shaft.

Figure 3C shows the inflatable retraction device with its inflatable chamber in its expanded state.

Figure 3D shows a version of the inflatable retraction device made using a modified Foley catheter in its collapsed state.

Figure 3E shows a version of the inflatable retraction device made using a modified Foley catheter in its expanded state.

Figure 4A shows an inflatable retraction device according to the invention that provides a retraction force from outside the body with its inflatable chamber in its collapsed state, prior to insertion into the abdomen.

Figures 4B through 4E show a longitudinal cross-section of the abdomen with the inflatable retraction device shown in figure 4A, wherein:

Figure 4B shows the inflatable retraction device after insertion adjacent to the liver.

Figure 4C shows the inflatable retraction device in contact with the liver after inflation of the inflatable chamber to its expanded state.

Figure 4D shows the inflatable retraction device being manipulated to retract the liver.

Figure 4E shows the inflatable retraction device clamped to a bar to maintain the liver in its retracted position.

Figure 5A shows an inflatable paddle retractor according to the invention that provides a retraction force from outside the body cavity and has a substantially flat inflatable chamber.

Figure 5B shows one configuration of inflatable chamber of the inflatable retraction device shown in figure 5A.

Figure 5C shows an alternative configuration of the inflatable chamber of the inflatable retraction device shown in figure 5A.

Figure 5D shows details of the shaft of the inflatable retraction device shown in figure 5A.

Figure 5E shows details of the inflation coupler of the inflatable retraction device shown in figure 5A.

Figure 5F shows the sheath for the inflatable retraction device shown in figure 5A.

Figure 5G shows the inflatable chamber of the inflatable retraction device shown in figure 5A retained in its rolled state by detachable lacing.

Figure 5H is a cross-section of the inflatable chamber shown in figure 5B, showing tacking connecting opposite faces of the envelope.

Figures 6A through 6D show a longitudinal cross-section of the abdomen with an inflatable paddle retractor according to the invention, wherein:

Figure 6A shows the inflatable paddle retractor after insertion adjacent to the liver.

Figure 6B shows the inflatable paddle retractor in its expanded state in contact with the liver.

Figure 6C shows the inflatable paddle retractor being manipulated to retract the liver.

Figure 6D shows the inflatable paddle retractor clamped to a bar to maintain the liver in its retracted position.

Detailed Description of the Invention

1. Free Balloon Inflatable Retraction Devices

(a) Free Balloon Inflatable Retraction Device

Figures 1A and 1B show a free balloon inflatable retraction device according to a first aspect of the invention. The free balloon inflatable retraction device is inserted in a collapsed state into a part of the body, such as the abdomen, adjacent to the organ to be retracted. The free balloon inflatable retraction device is inserted into the body through a trocar inserted into a single small incision about 10 - 20 mm long in the body wall. Once in place, the free balloon retractor is inflated into an expanded state to retract the organ.

Figure 1A shows the inflatable retraction device 1 in its expanded state. The envelope 6 encloses the inflatable chamber 11. The envelope 6 is made of a relatively inelastic and tough film of a plastic such as Mylar®, polyethylene, or polyurethane. The preferred material for the envelope is a polyethylene and nylon composite. The thickness of the envelope is typically from 0.5 to 5 mils (13 to 130 microns). The envelope can be a polyhedral structure constructed from two segmented, substantially flat pieces of plastic film, which gives the inflatable chamber a substantially polyhedral shape. Alternatively, two non-segmented,

substantially flat pieces of plastic film can be used to make a relatively flat inflatable chamber. In a further alternative, two curved pieces of plastic film can be used to give the inflatable chamber a substantially spherical or spheroidal shape. Preferably, the envelope is made of an elastomeric material, such as latex or silicone rubber, and the inflatable chamber is substantially spherical or spheroidal, as shown in figure 1A.

The inflation tube 16 is sealed into the envelope 6. The inflation tube is preferably a rigid tube of metal or plastic having an outside diameter suitable for passing through a trocar. Alternatively, if a suitable manipulable introducer sleeve is used to place the inflatable retraction device in its collapsed state adjacent to the organ to be retracted, the inflation tube 16 can be made of a flexible material such as plastic or rubber.

The inflation tube 16 allows an inflation fluid to pass into and out of the inflatable chamber 11. The inflation fluid is preferably a gas, typically air, nitrogen or carbon dioxide, although a liquid, such as saline solution, or other suitable gases may be used. Typical inflation pressures are in the range 0.3 to 0.7 psi (0.21 to 0.48 Pa), the preferred pressure being 0.5 psi (0.35 kPa). Once the inflatable chamber is fully inflated, and the organ has been retracted, the inflation pressure can be reduced to about 0.3 psi (0.21 kPa) to maintain the organ in its retracted state. The proximal end of the inflation tube 16 is provided with a valve 21 which controls the flow of inflation fluid.

The inflatable retractor is shown in its collapsed state in figure 1B. The main envelope (not shown) is packed in a collapsed state, and is maintained in its packed state by the sleeve 26 and the detachable lacing 31. The sleeve 26 can alternatively be fitted with a tear strip (not shown) or detachable lacing can be used alone without a sleeve. As a further alternative, the packed main envelope can be accommodated within the inflation tube 16. The cord 36 releases the detachable lacing, but remains attached to the sleeve 26 so that cord can be used to withdraw the sleeve from the body.

(b) Method of Using a Free Balloon Inflatable Retraction Device

The method according to the invention of using a free balloon inflatable retraction device according to the first aspect of the invention to separate the bowel and the liver to gain access to observe the gall bladder will now be described with reference to figures 2A and 2B.

The free balloon inflatable retraction device 1 is supplied with its envelope (not shown) packed in a collapsed state, and maintained in its collapsed state by the sleeve 26. Two small incisions I1 and I2, each about 10 - 20 mm long, are made in the abdominal wall AW, as shown in figure 2A. A trocar T1, suitable for receiving the free balloon inflatable retraction device 1 in its collapsed state, is driven through the incision I1 into the abdomen. An additional trocar T2, suitable for receiving the endoscope E, is driven through the incision I2 into the abdomen.

The endoscope E is inserted into the trocar T2 and positioned so that the intended deployment site of the free balloon inflatable retraction device 1 can be seen. The proximal end of the inflation tube 16 of the retractor is grasped and used to insert the distal end of the inflation tube and the packed envelope 29 of the inflatable chamber into the trocar T1. The inflation tube is advanced until the packaged envelope lies suitably positioned between the liver L and the bowel B, as shown in figure 2A.

The envelope 6 of the inflatable chamber is released from the sleeve 26 by pulling the cord 36 to detach the detachable lacing 31. A supply of a suitable inflation fluid (not shown) is connected to the inflation tube 16. The valve 21 is turned on to allow the inflation fluid to pass through the inflation tube into the inflatable chamber 11. The inflation fluid expands the inflatable chamber to its expanded state, as shown in figure 2B. The expanding inflatable chamber 11 lifts the liver L in the direction shown by the arrow 41, and retracts the bowel B in the direction indicated by the arrow 46.

The expanding inflatable chamber 11 of the free balloon inflatable retraction device 1 lifts the liver L by exerting a force against the bowel B, and retracts the bowel B by exerting a force against the liver L. Little, if any, of the retraction force is provided by the inflation tube 16.

The relative movement of the liver L and the bowel B opens up a passage through which the endoscope E can be advanced to observe the gall bladder GB, as shown in figure 2B. Figure 2C is a plan view showing the off-center placement of the incision I2 which allows the endoscope E to pass to the side of the inflatable chamber 11 to observe the gall bladder GB. Additional small incisions can be made to receive trocars through which other instruments can be inserted to treat the gall bladder.

2. INFLATABLE RETRACTION DEVICES PROVIDING A RETRACTION FORCE FROM OUTSIDE THE BODY

(a) Substantially Spherical External Inflatable Retraction Device

Figures 3A through 3E show some variations on an inflatable retraction device that provides a retraction force from outside the body. The inflatable retraction device is inserted into a part of the body, such as the abdomen, through a trocar inserted into a single small incision about 10 - 20 mm long in the body wall. The inflatable retraction device provides a relatively large surface area over which a retraction force provided from outside the body is applied.

The inflatable retraction device 2, shown in its inflated state in figure 3C, comprises a small (about 2" (50 mm) diameter) inflatable chamber 7 on the distal end of a hollow cylindrical plastic or metal shaft 12 about 0.2" (5 mm) in diameter. The inflatable chamber has an envelope 9 preferably of an elastomeric material, such as latex, but the envelope can be made of a non-elastic material such as polyethylene, polyurethane, Mylar®, or a polyethylene and nylon composite. The shaft 12 fits inside a standard 5.5 mm internal diameter trocar. The proximal end of the shaft 12 includes a fitting 17 to which a source of inflation fluid (not shown) can be attached. The fitting 17 includes a valve 22 that enables the inflatable chamber 7 to be maintained in its inflated state when the source of inflation fluid is disconnected.

Figures 3A and 3B show the inflatable retraction device 2 with its inflatable chamber 7 in two alternative collapsed states. In figure 3A, the envelope (not shown) of the inflatable chamber is packed into a small volume and is held in its packed state by the sleeve 27. The sleeve 27 is held in place by the detachable lacing 32. The detachable lacing is detached by pulling the cord 37. Alternatively, the sleeve 27 can include a tear strip (not shown), or the envelope can be held in its packed state by detachable lacing alone, or by some other suitable means. The packed envelope forms a linear extension of the shaft 12.

In figure 3B, the envelope 9 of the inflatable chamber is attached to the distal end of the shaft 12 and a low vacuum is applied to the fitting 17 to draw the envelope up inside the bore of the shaft 12. Once the envelope has been stored in the shaft 12, the vacuum may be released. Internal storage of the envelope of the inflatable chamber is preferred, and is particularly suitable if the envelope is made of an elastomeric material. With a non-elastomeric envelope, the

envelope must be packed before it is drawn into the bore of the shaft. Internal storage cannot be used if the packed envelope is too bulky to fit in the bore of the shaft 12.

(b) Method of Making an External Inflatable Retraction Device by Modifying a Foley Catheter

An inflatable retractor of the type just described for providing a retraction force from outside the body can be made by modifying a Foley catheter, as shown in figures 3D and 3E. A Foley catheter has an elastomeric inflatable chamber 42 on the end of a flexible catheter 47. The inflatable chamber of the Foley catheter provides the inflatable chamber 7 (figure 3C) of the inflatable retractor. The catheter of an unmodified Foley catheter, even when inflated, is too flexible to allow the Foley catheter to apply a useable retraction force. A modified Foley catheter according to the invention is shown in its collapsed state in figure 3D, and in its expanded state in figure 3E. The Foley catheter is modified by inserting a stylet 52 into the catheter 47. The stylet is preferably inserted such that the distal end 57 of the stylet substantially coincides with the distal end 62 of the catheter, i.e., the junction of the catheter 47 and the inflatable chamber 42. The rigid stylet together with the flexible catheter provides the shaft 12 (figure 3C) of the inflatable retraction device and enables the modified Foley catheter to be used to retract organs.

(c) Method of Using a Substantially Spherical External Inflatable Retraction Device

A method of using an inflatable retraction device of the type shown in figures 3A-3C to lift the liver so that the gall bladder can be observed will now be described with reference to figures 4A through 4E. The method can also be practiced using an inflatable retraction device made by modifying a Foley catheter.

The inflatable retraction device 62 is supplied with its inflatable chamber 67 in a collapsed state. The envelope (not shown) of the inflatable chamber is packed so that it forms a linear extension of the shaft 72, as shown in figure 4A. The envelope is retained in its packed state by the sleeve 77 and the detachable lacing 82. Alternatively, a sleeve with a tear strip, detachable lacing alone, or some other suitable means, can be used. Alternatively, the envelope can be mounted inside the tube 72, as shown in figure 3B.

Referring to figure 4B, an incision I1 is made in the abdominal wall AW and a 5.5 mm external diameter trocar T1 is driven through the abdominal wall. A second incision I2 is made so that a suitable endoscope E can be inserted into the abdomen through an additional trocar T2. The cord 87 attached to the detachable lacing 82 is run along the length of the tube 72.

The proximal end of the shaft 72 is then grasped and manipulated to insert the packed envelope 70 and the distal part of the shaft into the abdomen through the trocar T1. Once the packed envelope has passed through the trocar T1, the proximal end of the shaft 72 is manipulated to bring the packed envelope 70 close to the liver L. The shaft is then temporarily clamped in position by attaching it to a suitable bar (not shown).

The cord 87 is pulled to detach the detachable lacing 82 from the sleeve 77. This releases the sleeve from around the packed envelope 70. The cord and detachable lacing remain attached to the sleeve so that the sleeve can be withdrawn from the abdominal cavity through the trocar T1, either immediately or at the end of the operation.

A source of inflation fluid is attached to the fitting 92. The preferred inflation fluid is air, although a different gas, such as carbon dioxide, or a liquid, such as saline solution, can be used. The valve 99 is turned on to enable inflation fluid to flow through the bore of the shaft 72 into the inflatable chamber 67. This releases the envelope 69 from its packed state and inflates the inflatable chamber into its expanded condition, as shown in figure 4C. When the inflatable chamber is fully expanded, the valve 99 is preferably turned off and the source of inflation fluid is disconnected. Alternatively, the source of inflation fluid can be left connected and the valve 99 left turned on.

The proximal end of the shaft 72 is gripped by the hand H, the shaft 72 is detached from the bar, and, while observing through the endoscope E, the proximal end of the shaft 72 is manipulated to engage the inflated inflatable chamber 67 with the liver L. The shaft 72 is then further manipulated to push the inflated inflatable chamber 67 against the liver, as shown in figure 4D. The force applied to the liver by the relatively large area of the inflatable chamber gently retracts the liver so that the gall-bladder GB can be seen through the endoscope E. When the liver is suitably retracted, the shaft 72 is once more clamped to the bar B to hold the liver in its retracted condition, as shown in figure 4E.

After observation has been completed, the proximal end of the shaft 72 is once more gripped and the shaft is released from the bar B. The shaft is then manipulated to allow the liver to return to its normal, non-retracted position. The valve 99 is operated to release the inflation fluid from the inflatable chamber. The fitting 92 is also preferably connected to a low vacuum to further collapse the inflatable chamber 67. With the inflatable chamber fully collapsed, the valve 99 is returned to its off position. The proximal end of the shaft 72 is manipulated to withdraw the inflatable chamber 67 and shaft 72 from the abdomen through the trocar T1. The cord 87, detachable lacing 82, and sheath 77 are withdrawn from the abdomen through the trocar T1 by pulling on the cord 87. Finally, the trocars are withdrawn from their respective incisions.

(d) Paddle Retractor

In some procedures, the substantially spherical shape of the inflatable retraction devices just described causes them to obstruct access to the tissue to be treated. The paddle retractor 3 shown in figure 5A has a considerably more compact inflatable chamber than a substantially spherical inflatable retraction device. The more compact inflatable chamber provides a large surface area to engage the organ but is less likely to obstruct access to the tissue. The paddle retractor is inserted into a part of the body, such as the abdomen, through a trocar inserted into a single small incision about 10 - 20 mm long in the body wall.

The paddle retractor 3 has a flat, rectangular, inflatable chamber 8 attached to a hollow shaft 13. The inflatable chamber 8 is enclosed by an envelope 18 made of molded cellophane, about 0.002" to 0.005" (0.05 to 0.125 mm) thick. Other materials that are capable of being collapsed into a relatively small volume but which conform to a molded shape when inflated can be used. Figure 5B shows a version of the inflatable chamber 8A having a length of about 3.2" (80 mm) and a width of about 0.8" (20 mm). The thickness of the inflatable chamber is about 0.2" (5 mm). Opposite faces of the envelope 18A may be tacked together with the tacks 9, and as additionally shown in the cross-sectional view in figure 5H, to prevent the inflatable chamber 8A of the paddle retractor from ballooning out when inflated.

An alternative inflatable chamber 8B is shown in figure 5C. This inflatable chamber has a length of about 2.4" (60 mm), a width of about 2" (50 mm), and

a thickness of about 0.2" (5 mm). The alternative inflatable chamber may have the same construction as the inflatable chamber shown in figure 5B.

Returning to figure 5A, the envelope 18 is attached to the coupler 23, preferably by welding. The coupler 23 is made of metal, preferably stainless steel, is hollow, and internally threaded, as can be seen in figure 5C.

The threads in the coupler 23 accept the external threads 28 on the distal end of the shaft 13 (figure 5D).

The shaft 13, shown in detail in figure 5D, has an internal bore about 0.1" (2.5 mm) in diameter. The shaft 13 has an external diameter of about 0.18" (4.5 mm) and a length that depends on the application. The range of lengths is from about 6" (150 mm), for use in upper abdominal operations, to about 12" (300 mm), which reach to the pelvis for carrying out such operations as appendectomy. The proximal end of the shaft 13 also carries external threads 33.

The external threads 33 of the shaft 13 are screwed into a coupler 38, which forms part of the inflation adapter 43, shown in detail in figure 5E. The coupler is similar to the coupler 23, and has one end of a short length of 0.12" (3 mm) outside diameter plastic tubing 48 attached to it. The plastic tubing is preferably polyethylene, and the preferred attachment method is welding. Similarly attached to the other end of the plastic tube is a reflux valve 53, which includes the coupler 58, suitable for accepting a syringe (not shown).

The shaft 13 may be attached directly to the envelope 18 of the inflatable chamber 8 and to the inflation adapter 43, instead of via the couplers 23 and 38. However, it is preferred that the shaft 13 be detachable from the envelope 18 and the inflation adapter 43, which necessitates using the couplers 23 and 38. This way, the envelope 18 and the inflation adapter 43 can be disposable and the shaft 13 and the sheath 63 can be re-sterilized for further use.

The sheath 63 has an external diameter of about 0.22" (5.5 mm), an internal diameter of about 0.18" (4.5 mm) and a length of about 6" (150 mm). The proximal end of the sheath 63 is fitted with the flange 68, which is about 1" (25 mm) in diameter. The sheath fits inside a standard 5.5 mm internal diameter trocar and projects about 0.1" (2.5 mm) beyond its end.

(e) Method of Using a Paddle Retractor

A method of using a paddle retractor to lift the liver so that the gall bladder can be observed will now be described.

The paddle retractor 3 is supplied with the envelope of the main inflatable chamber in a rolled state such that it forms a linear extension of the coupler 23, as shown in figure 5G. The envelope is retained in its rolled state by the sleeve 68 and the detachable lacing 73. Alternatively, a sleeve with a tear strip, or detachable lacing alone, can be used.

An incision I1 is made in the abdominal wall AW and a 5.5 mm external diameter trocar T1 is driven through the abdominal wall. The sheath 63 is then inserted into the trocar T1. A second incision I2 is made so that a suitable additional trocar T2 can be inserted into the abdomen. An endoscope E is inserted through the trocar T2 to observe the retraction procedure.

The inflatable retraction device is assembled by attaching the couplers 23 and 38 to the distal and proximal ends, respectively, of the shaft 13. The cord 78 attached to the detachable lacing 73 is run along the length of the shaft 13.

The proximal end of the shaft 13 is then grasped and manipulated to insert the rolled envelope 18 and the distal end of the shaft into the abdomen through the sheath 63. Once the rolled envelope 18 has passed through the sheath 63, the proximal end of the shaft 13 is manipulated to bring the rolled envelope close to the liver, as shown in figure 6B. The shaft 13 is then temporarily clamped in position by attaching it to a suitable bar.

The cord 78 is pulled to detach the detachable lacing 73 from the sleeve 68. This releases the sleeve from around the rolled envelope 18. The cord and detachable lacing remain attached to the sleeve so that the sleeve can be withdrawn from the abdominal cavity through the sheath 63 either immediately or at the end of the operation.

A large syringe S, approximately 50 ml, is filled with an inflation fluid and attached to the coupler 58. The preferred inflation fluid is air, although a different gas, such as carbon dioxide, or a liquid, such as saline solution, can be used. The syringe is then operated to drive the inflation fluid through the reflux valve 53, the tube 48, and the shaft 13, into the inflatable chamber 8, as shown in figure 6B. This unrolls the envelope 18 and inflates the inflatable chamber 8. When the inflatable chamber is fully inflated, the syringe is detached from the coupler 58. The reflux valve closes automatically and maintains the inflation pressure in the inflatable chamber.

The proximal end of the shaft 13 is gripped, the shaft 13 is detached from the bar B, and, while observing through the endoscope E, the proximal end of the

shaft 13 is manipulated to engage the inflated inflatable chamber 8 with the liver L. The shaft 13 is then further manipulated to push the inflatable chamber against the liver. The force applied to the liver by the relatively large area of the inflatable chamber gently retracts the liver, as shown in figure 6C, so that the gall-bladder GB can be seen through the endoscope E. When liver is suitably retracted, the shaft 13 is once more clamped to the bar B, as shown in figure 6D.

After observation has been completed, the proximal end of the shaft 13 is once more gripped and the shaft is released from the bar. The shaft is then manipulated to disengage the inflatable chamber 8 from the liver and to allow the liver to return to its normal, non-retracted position. The syringe, in its empty position, is reconnected to the coupler 58, which opens the reflux valve 53. The syringe is operated to aspirate the inflation fluid from the inflatable chamber 8. The envelope 18 returns to its rolled position, which enables the proximal end of the shaft 13 once more to be manipulated to withdraw the inflatable retraction device from the abdominal cavity through the sheath 63. The cord 78, detachable lacing 73, and sheath 63 are withdrawn from the abdominal cavity through the sheath 73 by pulling on the cord 78. Finally, the sheath 63 is withdrawn from the trocar T1.

Claims

We claim:

1. An apparatus for retracting an organ inside the body to gain access to an adjacent tissue, the apparatus comprising:

an inflatable chamber means capable of being inserted into the body through a small incision in a collapsed state, the inflatable chamber means having a thin, flexible main envelope, and

inflating means for selectively inflating the inflatable chamber means to an expanded condition while in place within the body.

2. The apparatus of claim 1, wherein the main envelope includes a substantially non-elastic material.

3. The apparatus of claim 1, wherein the main envelope includes an elastomeric material.

4. The apparatus of claim 1, wherein the inflating means comprises a flexible tube sealed into the main envelope.

5. The apparatus of claim 1, wherein the inflating means comprises a rigid tube sealed into the main envelope.

6. An apparatus for providing a retraction force from outside the body to retract an organ inside the body to gain access to an adjacent tissue, the apparatus comprising:

an inflatable chamber means for engaging the organ; and

a shaft means for manipulating the inflatable chamber means to retract the organ, the shaft means including:

a distal end to which the inflatable chamber means is attached,

a bore means, communicating with the inflatable chamber, for inflating the inflatable chamber to an expanded state when the inflatable chamber is in place within the body, and

a proximal end, the proximal end remaining outside the body when the inflatable chamber is in place in the body.

7. The apparatus of claim 6, wherein the inflatable chamber means is flat, and substantially oblong.

8. The apparatus of claim 7, wherein the inflatable chamber means has a width, a length, and a thickness, and the thickness of the inflatable chamber means is less than one tenth of the longer of the width or the length of the inflatable chamber.

9. The apparatus of claim 6, additionally comprising a reflux valve means, attached to the proximal end of the shaft means, for maintaining the inflatable chamber in its inflated state.

10. The apparatus of claim 6, wherein
the inflatable chamber is defined by an envelope,
the envelope is rolled when the inflatable chamber is in its collapsed state.

11. The apparatus of claim 10, additionally comprising detachable means for maintaining the envelope in its rolled state, the detachable means being detached before the inflatable chamber is inflated to its expanded state.

12. The apparatus of claim 6, wherein the inflatable chamber means is substantially spherical when in its expanded state.

13. The apparatus of claim 6, comprising:
a Foley catheter having an inflatable portion and a flexible tube, the inflatable portion of the Foley catheter providing the inflatable chamber means; and
a stylet inserted into the flexible tube, the stylet and the flexible tube of the Foley catheter together providing the shaft means.

14. A method for retracting an organ in the body in the course of treating adjacent tissue, comprising:

providing an inflatable retraction device in a collapsed state;

making a small incision in the body;

introducing the inflatable retraction device in a collapsed state into the body through the small incision;

placing the inflatable retraction device in a collapsed state adjacent to the organ, and

inflating the inflatable retraction device into an expanded state to retract the organ.

15. The method of claim 14, wherein the inflatable retraction device comprises:

an inflatable chamber means having a thin, flexible main envelope, and

means for selectively inflating the inflatable chamber to an expanded condition while in place within the body cavity.

16. The method of claims 14 or 15, wherein

the inflatable retraction device includes a detachable means for maintaining the inflatable retraction device in its collapsed state,

the method additionally includes providing an insertion tube,

the step of introducing the inflatable retraction device in a collapsed state into the body includes:

inserting the insertion tube into the body through the small incision, and

pushing the inflatable retraction device in a collapsed state through the insertion tube from outside the body, and

the step of placing the inflatable retraction device in a collapsed state adjacent to the organ additionally includes the step of detaching the detachable means to release the inflatable retraction device from its detached state.

17. The method of claim 16, wherein

the detachable means includes a peelable sheath,

the step of detaching the detachable means includes the step of peeling the peelable sheath away from the inflatable retraction device.

18. The method of claim 17, wherein

the peelable sheath includes a tear strip,

the step of peeling the peelable sheath includes the step of removing the tear strip to release the peelable sheath from the inflatable retraction device.

19. The method of claim 16, wherein

the detachable means includes removable lacing, and

the step of detaching the detachable means includes the step of releasing the removable lacing.

20. The method of claim 14, additionally comprising:

providing a surgical instrument;

making a second incision in the body; and

passing the surgical instrument through the second incision, past the inflated inflatable retraction device, to treat the tissue.

21. A method for providing a retraction force from outside the body to retract an organ in the body in the course of treating adjacent tissue, the method comprising:

providing an inflatable retraction device including an inflatable chamber, and a hollow shaft having a distal end and a proximal end, the inflatable chamber being attached to the distal end of the shaft in a collapsed state;

making a small incision in the body;

manipulating the proximal end of the shaft to pass the inflatable chamber and part of the shaft into the body through the small incision, and to place the inflatable chamber adjacent to the organ;

passing a fluid through the shaft to inflate the inflatable chamber into an expanded state; and

manipulating the proximal end of the shaft to engage the organ with the inflatable chamber and to retract the organ.

22. The method of claim 21, wherein

the step of providing an inflatable retraction device provides an inflatable retraction device additionally including a detachable means for maintaining the inflatable chamber in its collapsed state,

the method additionally includes the step of providing an insertion tube, and

the step of manipulating the proximal end of the shaft to pass the inflatable chamber and part of the shaft into the body, and to place the inflatable chamber adjacent to the organ includes the steps of:

manipulating the shaft to push the inflatable chamber and part of the shaft through the insertion tube from outside the body, and

detaching the detachable means from the inflatable retraction device.

23. The method of claim 22, wherein the detachable means includes detachable lacing, and

the step of detaching the detachable means from the inflatable retraction device includes releasing the detachable lacing.

24. The method of claim 22, wherein the step of providing a detachable means includes providing a peelable sheath, and

the step of detaching the detachable means from the inflatable retraction device includes peeling away the peelable sheath.

25. The method of claim 24, wherein the peelable sheath includes a tear strip, and

the step of detaching the detachable means from the inflatable retraction device includes removing the tear strip to release the peelable sheath.

26. The method of claim 21, wherein

the step of providing an inflatable retraction device provides an inflatable retraction device including an inflatable chamber having a substantially oblong face having a length and a breadth, and a thickness that is small compared with the length and breadth of the oblong face, and

the step of manipulating the shaft to engage the organ with the inflatable chamber includes engaging the organ with the oblong face of the inflatable chamber.

27. The method of claim 21, wherein the step of providing an inflatable retraction device provides an inflatable retraction device having a substantially spherical inflatable chamber.

28. The method of claim 21, wherein the step of providing an inflatable retractor includes:

providing a Foley catheter having an inflatable chamber and a flexible tube,

providing a stylet, and

inserting the stylet into the flexible tube to provide the shaft.

29. The method of claims 21, 26, 27, or 28, additionally comprising the step of clamping the proximal end of the shaft to maintain the organ in its retracted state.

30. A method of making an inflatable retraction device for providing a retraction force from outside the body to retract an organ inside the body to gain access to an adjacent tissue, the method comprising:

providing a Foley catheter comprising an inflatable chamber and a flexible tube;

providing a stylet; and

inserting the stylet into the flexible tube.

31. The method of claim 30, wherein

the flexible tube has a distal end adjacent to the inflatable chamber,

the stylet has a distal end, and

in the step of inserting the stylet into the flexible tube, the stylet is inserted such that the distal end of the stylet substantially coincides with the distal end of the flexible tube.

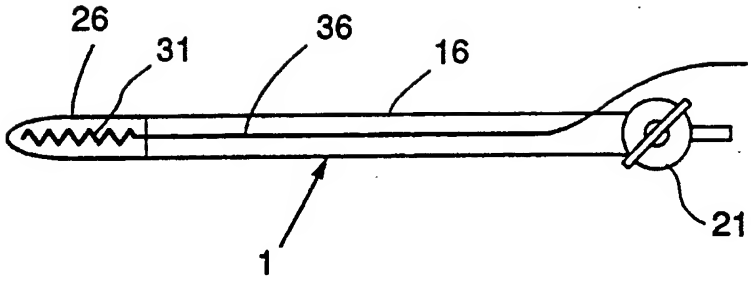


FIG. 1B

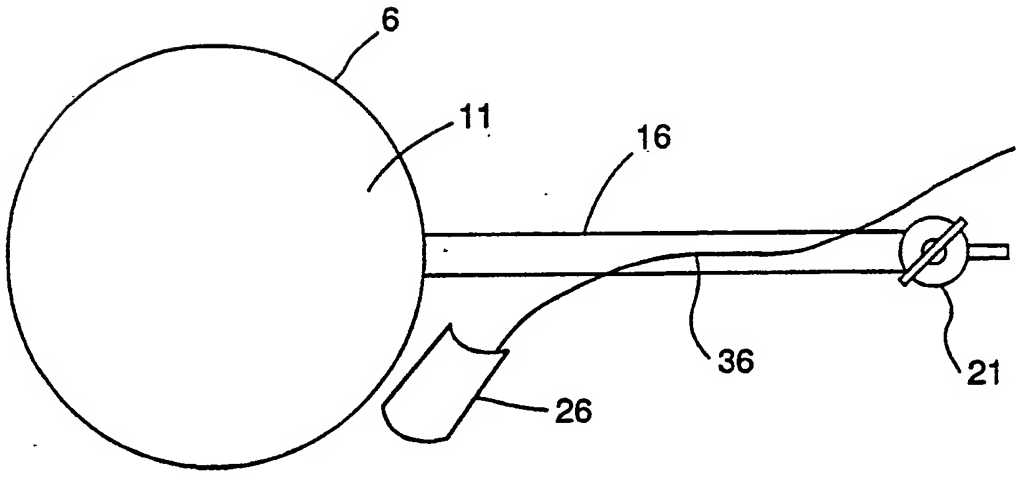


FIG. 1A

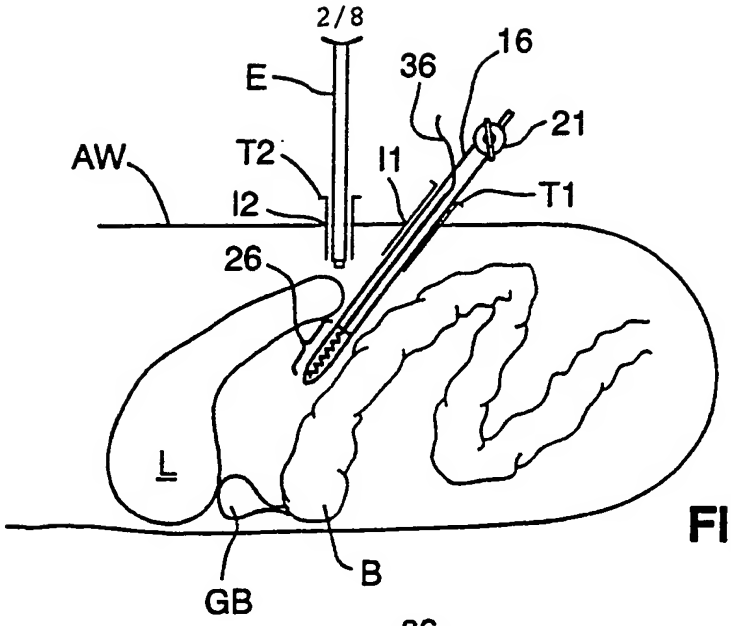


FIG. 2A

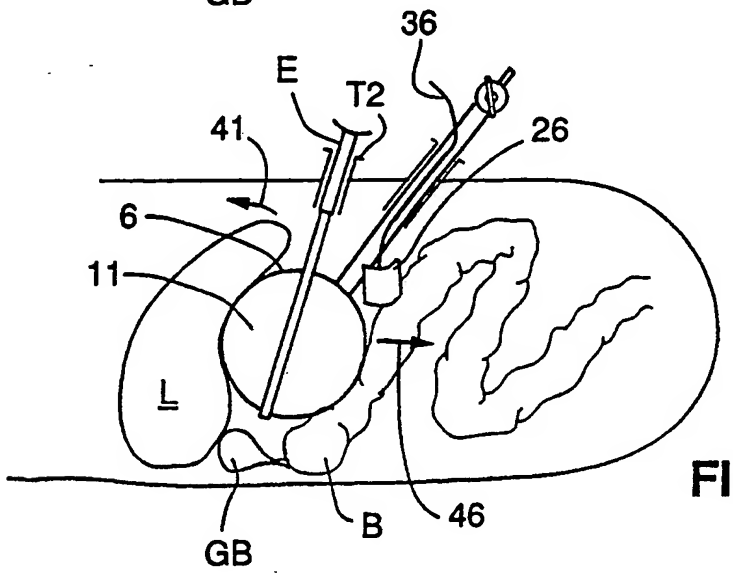


FIG. 2B

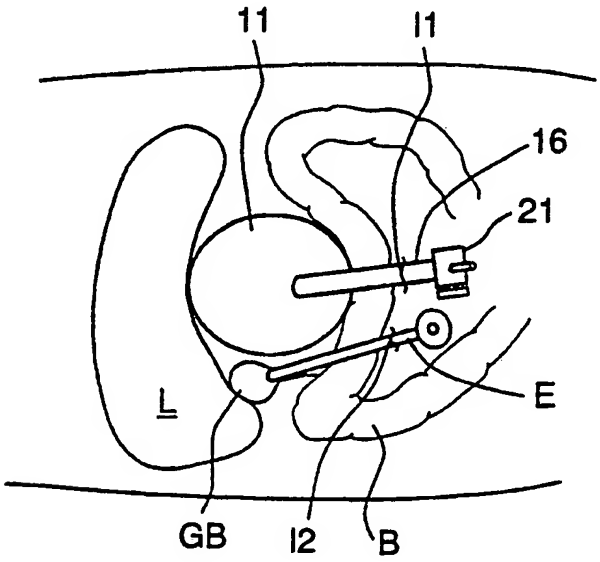


FIG. 2C

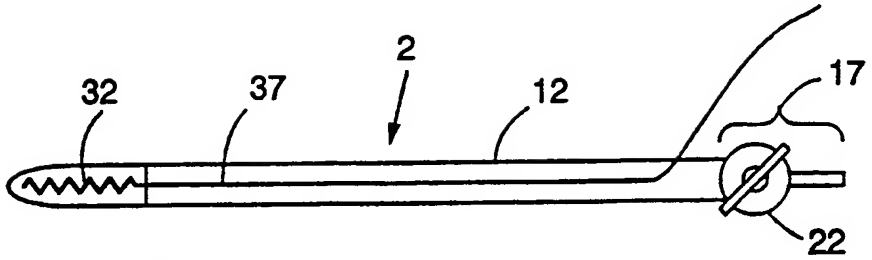


FIG. 3A

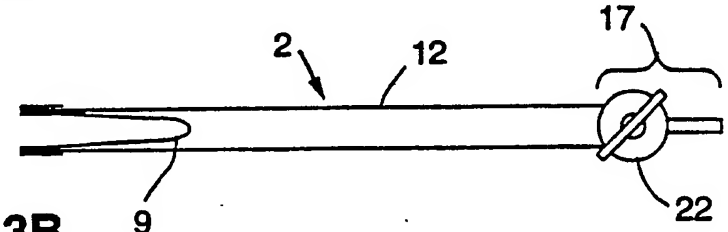


FIG. 3B

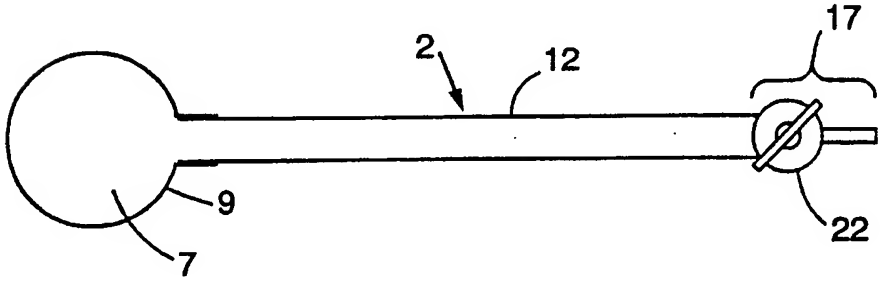


FIG. 3C

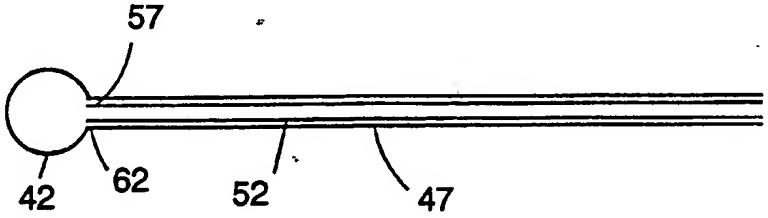


FIG. 3D

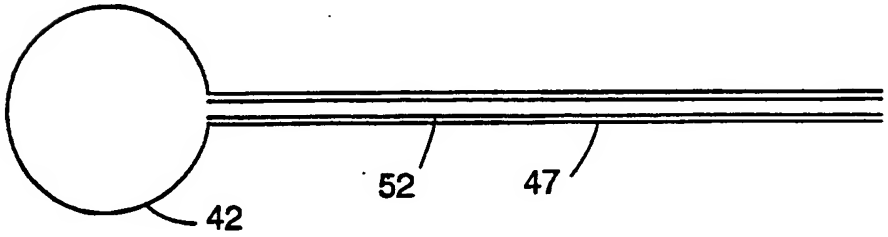


FIG. 3E

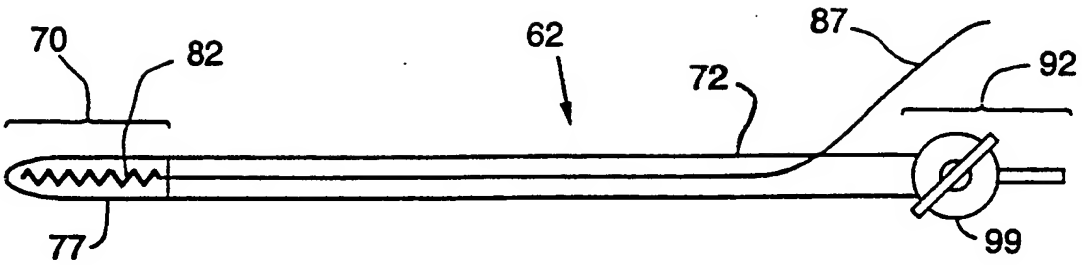


FIG. 4A

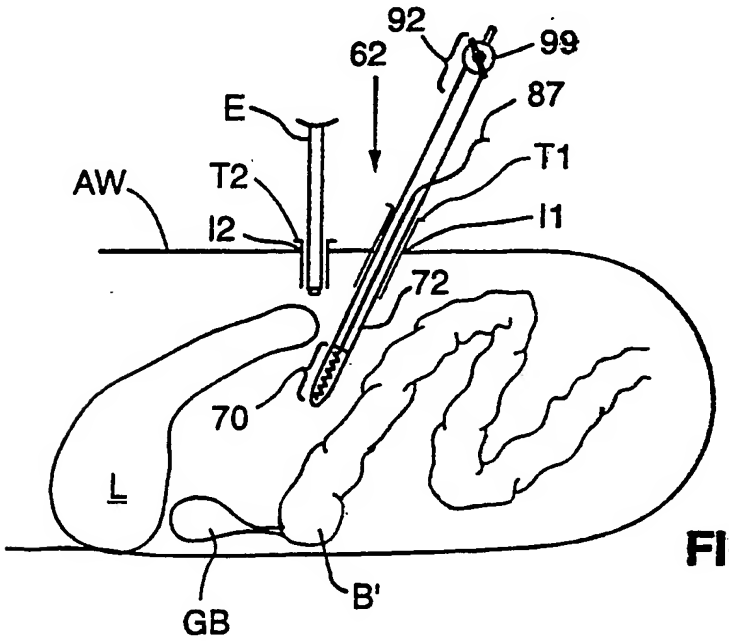


FIG. 4B

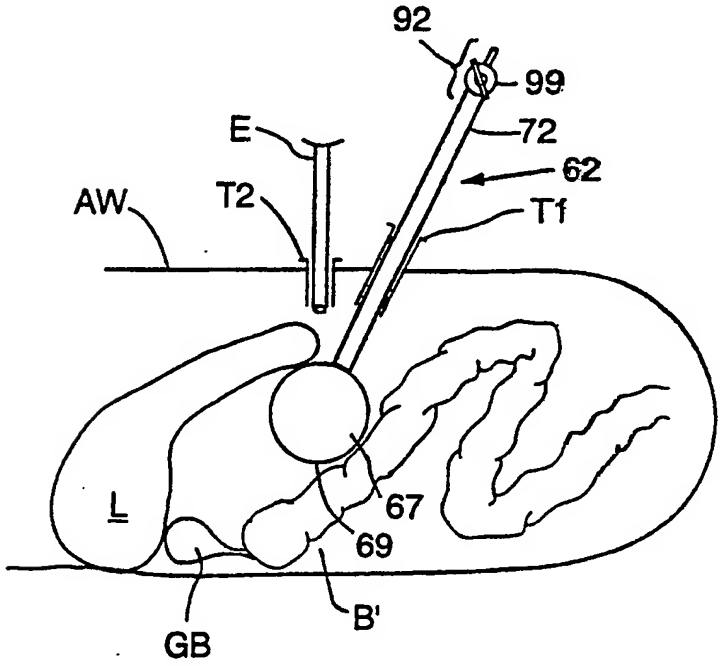


FIG. 4C

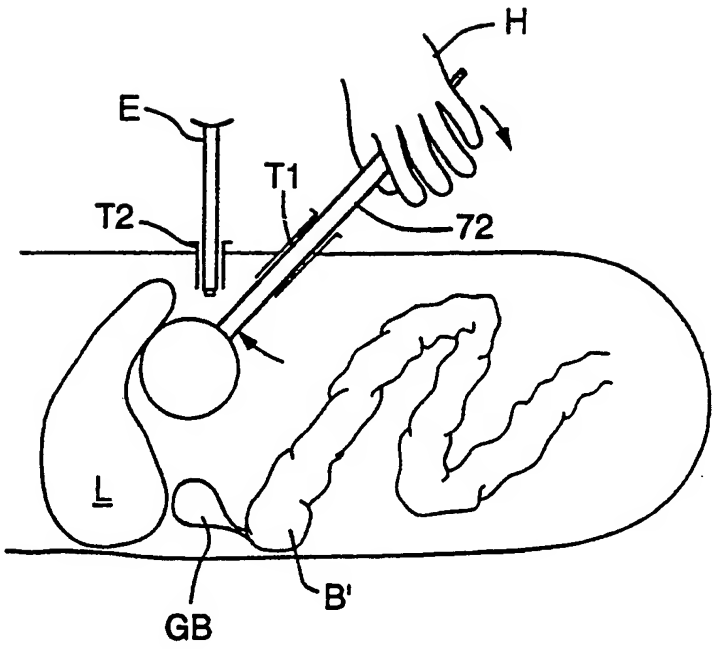


FIG. 4D

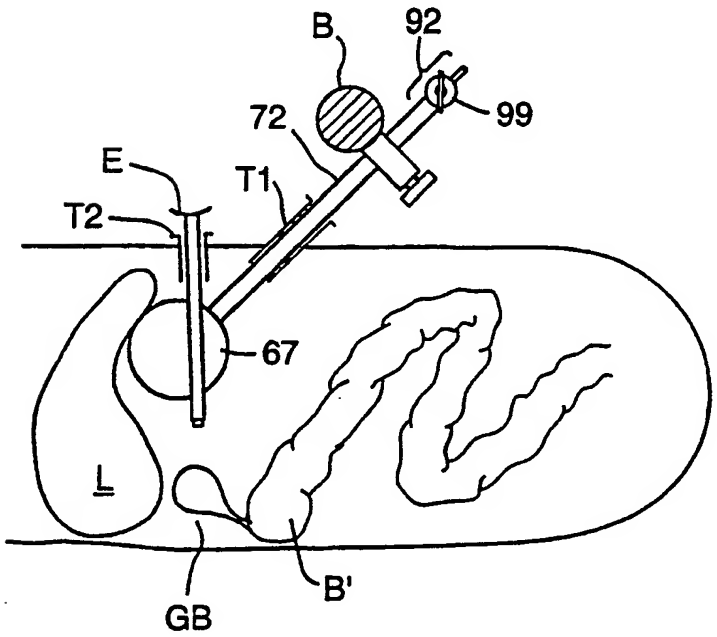


FIG. 4E

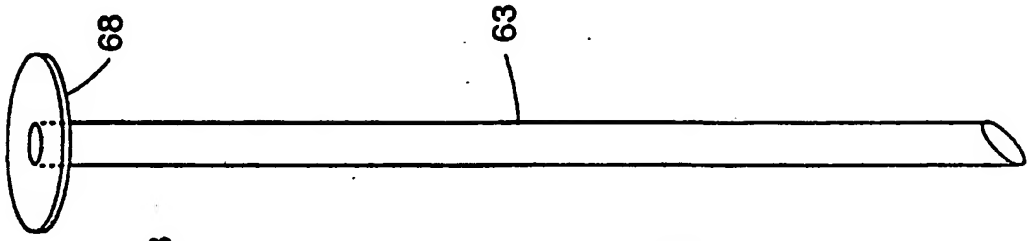


FIG. 5F

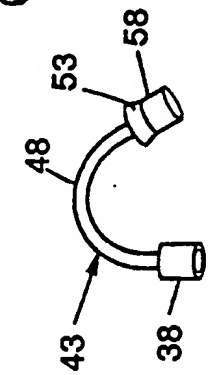


FIG. 5E

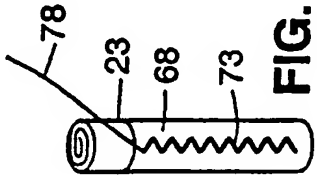


FIG. 5G

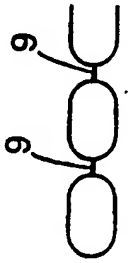


FIG. 5H

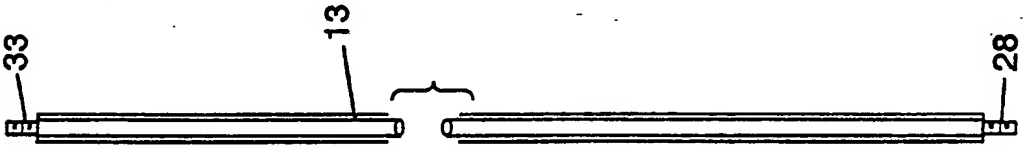


FIG. 5D

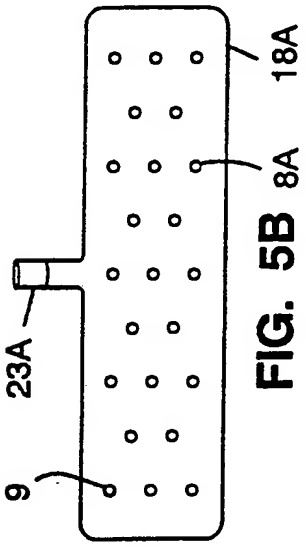


FIG. 5B

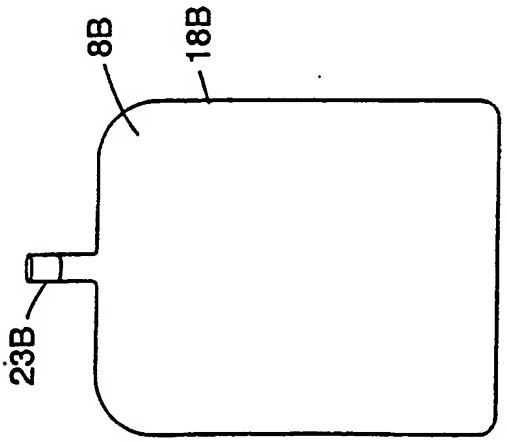


FIG. 5C

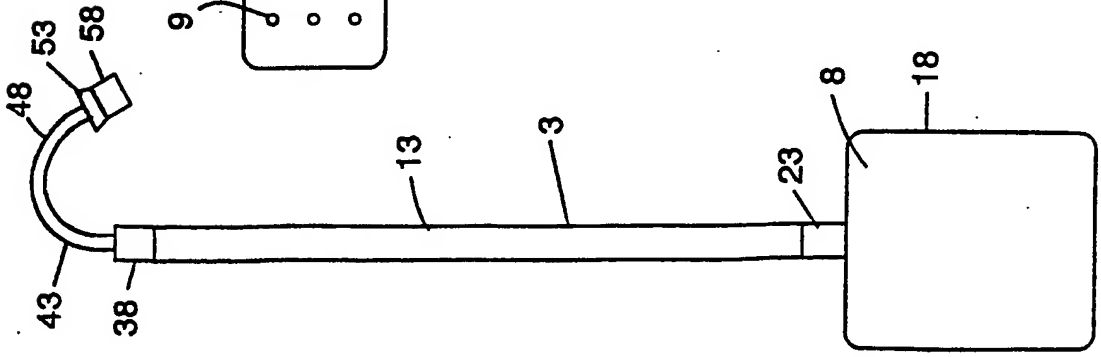
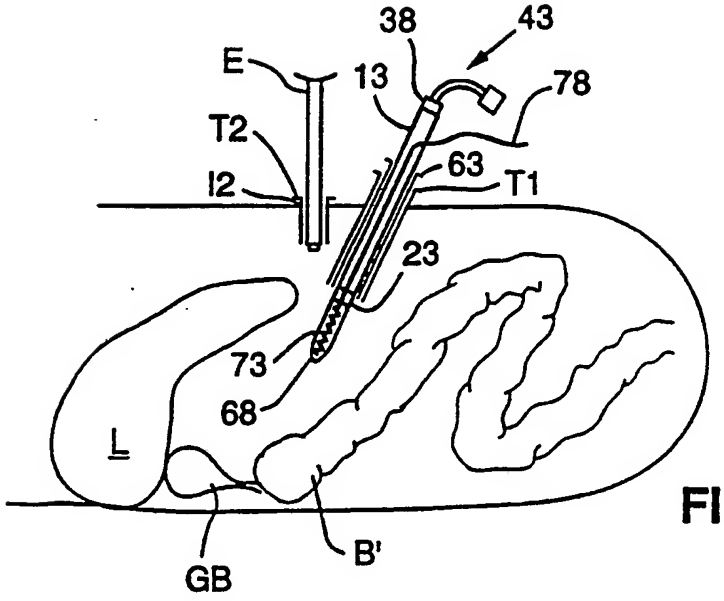


FIG. 5A


38
43
E
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78
T2
63
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I2
23
73
68
L
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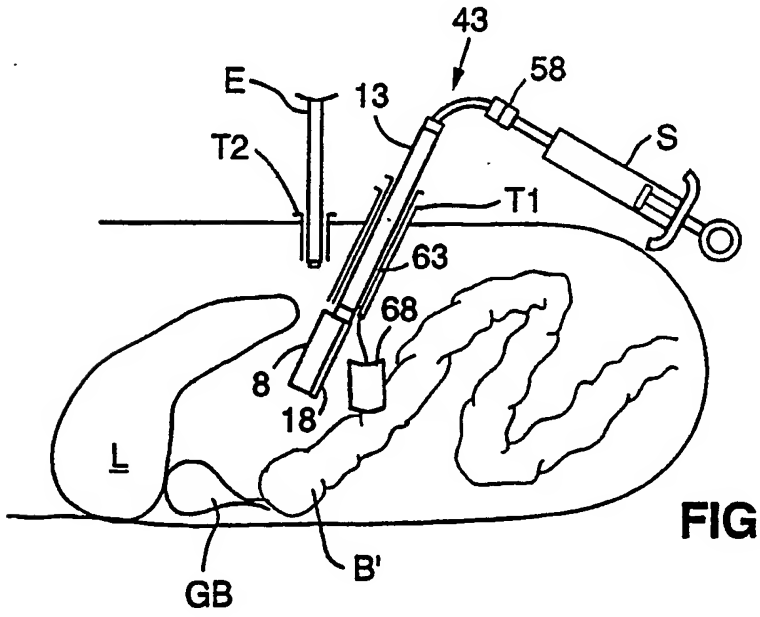
B'

FIG. 6A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T1
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FIG. 6B

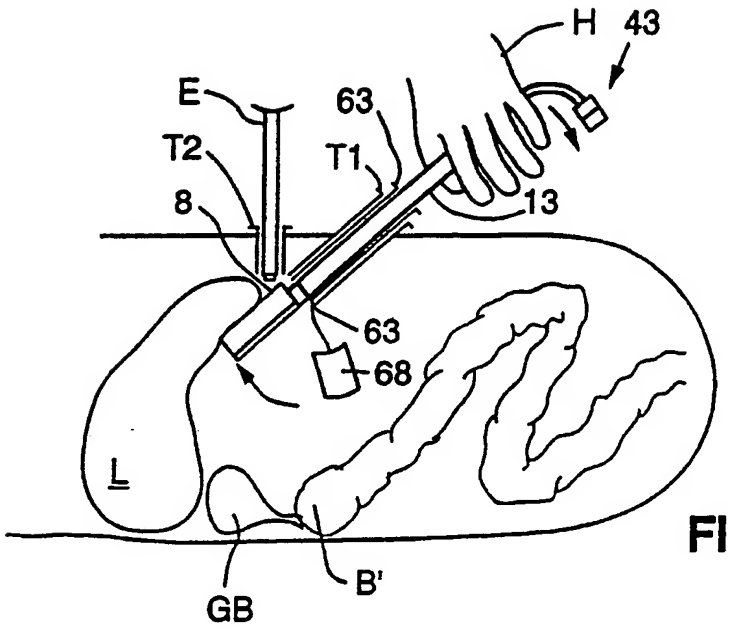

FIG. 6C

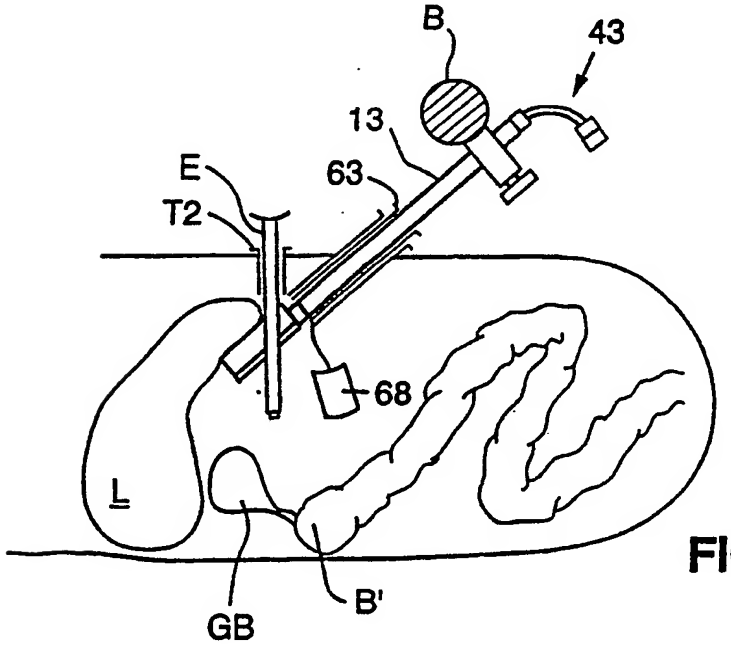

FIG. 6D

INTERNATIONAL SEARCH REPORT

International application No. PCT/US 92/04507

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl.5 A 61 B 17/02 A 61 B 1/32

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl.5	A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
Y	EP,A,0246086 (KLEIMAN) 19 November 1987, see column 4, line 50 - column 6, line 9; figures 1,2,4,6 ---	1-13,30 ,31
Y	US,A,4291687 (SINNREICH) 29 September 1981, see column 1, line 62 - column 2, line 44; figure 1 ---	1-13,30 ,31
A	DE,A,2847633 (OLYMPUS) 10 May 1979, see page 9, line 28 - page 10, line 5; figure 6 ---	1,6
A	US,A,3831587 (BOYD) 27 August 1974, see column 2, line 40 - column 3, line 23; figures 1,2 ---	1,6
A	US,A,3863639 (KLEAVELAND) 4 February 1975, see abstract; figures 1-3 --- -/-	1,6

° Special categories of cited documents :[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
10-09-1992	08. 10. 92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	MOERS R.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	US,A,4775371 (MUELLER, Jr.) 4 October 1988, see abstract; figures 1,5	13,30, 31
X,P	FR,A,2668695 (ETHNOR) 7 May 1992, see abstract; figures 1,2	1-13,30 ,31

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 9204507 SA 61166

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 01/10/92
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A- 0246086	19-11-87	None		
US-A- 4291687	29-09-81	None		
DE-A- 2847633	10-05-79	JP-C-	1322709	27-06-86
		JP-A-	54066582	29-05-79
		JP-B-	60051913	16-11-85
US-A- 3831587	27-08-74	None		
US-A- 3863639	04-02-75	None		
US-A- 4775371	04-10-88	None		
FR-A- 2668695	07-05-92	AU-A-	8706291	14-05-92
		EP-A-	0490714	17-06-92